REMARKS

Claims 1, 6-11, and 13-25 are currently pending. Claims 2-4 have been canceled without prejudice, and Applicants reserve the right to pursue the subject matter of these claims in this or other applications, for example, divisional or continuation applications. Claims 6 and 7 have been amended to correct claim dependencies. Claims 7 and 9 have also been amended to correct improper multiple dependencies, and new claims 24 and 25 have been added to recite the canceled limitations. Support for new claim 24 and 25 can be found in the specification at, for example, pages 6-7, paragraphs [0016]-[0017], and page 10, paragraph [0023] to page 11, paragraph [0026], and in original claims 6-9. The amendments to claims 6 and 7 and new claims 24 and 25 do not constitute new matter.

The Examiner has allowed claim 1.

The Examiner has rejected claims 3-4, 6-11, and 13-23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner has rejected claims 2-4, 6-11, and 13-23 under 35 U.S.C. § 112, first paragraph, for lack of enablement. For the reasons detailed below, the rejections should be withdrawn and the claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

The Claims Are Supported By The Specification

The Examiner has rejected claims 3-4, 6-11, and 13-23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the specification "does not describe the features of SEQ ID NO:1 that are retained by fragments and variants of SEQ ID NO:1 that are coupled to promoter activity."

Applicants note that claims 3 and 4 have been canceled, and that the claims no longer recite nucleic acids having at least 90% homology to or which bind at specific high stringency conditions to SEQ ID NO:1. As the basis for the rejection is obviated, Applicants submit that the rejection should be withdrawn.

Applicants are making the foregoing amendments with traverse, and believe that the Examiner's rejections are in error. The foregoing amendments are made in response to the final rejection and in order to advance prosecution, and Applicants reserve the right to pursue the canceled subject matter in this or other applications, for example, divisional or continuation applications. Applicants believe that the Examiner is utilizing an improper standard and is depriving Applicants of the proper scope of the subject matter of the invention, in particular, the subject matter contained in claims 3 and 4.

Applicants submit that the present disclosure satisfies the written description requirement by providing descriptions of the structural features of the nucleic acid sequences. To satisfy the written description requirement for a claimed genus, Applicants must disclose "a representative number of species by... disclosure of relevant identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or other physical and/or chemical properties, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." MPEP § 2163(II)(a)(ii) (citations omitted).

Applicants submit that the Examiner is improperly requiring that the specification disclose a link between the structure of the nucleic acid sequences and promoter function. Applicants note that disclosing a link between structure and function is merely one way of satisfying the written description requirement, but is not *always* required. See, *e.g.*, MPEP §

2163(II)(a)(ii). In the present case, as discussed in more detail below, the specification discloses structural characteristics sufficient to satisfy the written description requirement by relating molecules to SEQ ID NO:1 and providing a narrow range of variation from that specific sequence, either by requiring homology (90%) or hybridizability (under high stringency conditions). Since the specification also discloses methods for determining promoter activity, (for example, at page 4, paragraph [0013]), a person of ordinary skill in the art would be able to determine whether a given nucleic acid sequence had promoter activity based upon this disclosure. As such, based upon the specification, a person of ordinary skill in the art would understand that Applicants were in possession of the invention at the time of filing, because generating the nucleic acid sequences and testing them for promoter activity would be easily accomplished.

Applicants submit that this disclosure identifies specific structural characteristics of the nucleic acid sequences sufficient to satisfy the written description requirement. Applicants note that claims 3 and 4 provide for 90% homology to SEQ ID NO:1 and for binding to SEQ ID NO:1 under specific high stringency conditions, respectively. This disclosure also shows that the Applicants were in possession of the nucleic acid sequences, because it would be well within the abilities of a person of ordinary skill in the art to generate such nucleic acid sequences. While the Examiner states that "methods for preparing fragments or variants of SEQ ID NO:1 does not necessarily describe the nucleotide sequences of the fragments or variants prepared," the methods for preparing the nucleic acid sequences must be considered. See MPEP § 2163(II)(a)(ii) ("What constitutes a 'representative number' is an inverse function of the skill and knowledge in the art."). In the present case, because methods of identifying homology, hybridization, and promoter activity are well known in the art, the description of methods of

producing the nucleotide sequences is an important consideration. In the present case, the specification clearly recites methods of determining homology of a sequence at page 3, paragraph [0008]:

> "Sequence identity as defined herein is measured using the program Clustal W described by Thompson et al. (1994) Nucleic Acid Research 22:4673 and may be calculated using the EMBL Nucleotide Sequence Database."

Similarly, the specification describes specific high stringency conditions as well as methods of testing for promoter activity. See specification at, for example, pages 3-4, paragraphs [0010] and [0013]. Accordingly, a person of ordinary skill in the art would be capable of determining whether a given sequence was 90% homologous to SEQ ID NO:1 or whether a given sequence is capable of binding to SEQ ID NO:1 under the high stringency hybridization conditions, and would further be capable of testing the nucleotide sequence for promoter activity. Thus, because the skill and knowledge in the art of determining homology, hybridization, and promoter activity is very high, only one species (*e.g.*, SEQ ID NO:1) must be disclosed in order to satisfy the written description requirement.

For the foregoing reasons, Applicants submit that the Examiner is in error, and respectfully request reconsideration of the rejection for lack of support in the written description.

The Claims Are Enabled

The Examiner has rejected claims 2-4, 6-11, and 13-23 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that the specification fails to "provide guidance with respect to the identity and location of key nucleotides and regulatory regions required for promoter function that would be retained by fragments or variants of the sequence of SEQ ID NO:1."

Applicants note that claims 2-4 have been canceled, and that the claims no longer recite fragments of SEQ ID NO:1, nor do they recite nucleic acids having at least 90% homology to or which bind at specific high stringency conditions to SEQ ID NO:1. As the basis for the rejection is obviated, Applicants submit that the rejection should be withdrawn.

Applicants are making the foregoing amendments with traverse, and believe that the Examiner is in error. The foregoing amendments are made in response to the final rejection and in order to advance prosecution, and Applicants reserve the right to pursue the canceled subject matter in this or other applications, for example, divisional or continuation applications. For the reasons described below, Applicants believe that the Examiner is utilizing an improper standard and is depriving Applicants of the proper scope of the subject matter of the invention, in particular the subject matter contained in claims 3 and 4.

Applicants assert that the Examiner is improperly requiring that the specification disclose a link between the structural features claimed in claims 3 and 4 with the disclosed promoter activity. To satisfy the enablement requirement, the claimed invention must be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d. at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Evaluation of undue experimentation involves, but is not limited to the following factors: breadth of the claims, nature of the invention, state of the prior art, level of one of ordinary skill, level of predictability, amount of direction provided by the inventor, existence of working examples and the quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d. at 731, 8 USPQ2d at 1400 (Fed. Cir. 1988).

Applicants submit that it would require no more than routine experimentation to identify sequences falling within the scope of the claims. As discussed above, the specification

specifically provides methods of determining sequence homology, methods of determining hybridization under high stringency conditions, and methods of identifying promoter activity, all of which are well known in the art. The Examiner states that it would be "unpredictable whether fragments or variants of the sequence of SEQ ID NO:1 would retain promoter function," and that testing different nucleic acid sequences constitutes a "trial and error approach... [which] would constitute undue experimentation." Applicants note that experimentation is not undue if it is routine experimentation, and that a large volume of experimentation is acceptable if it is merely routine. See MPEP § 2164.06 ("The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine."). As discussed above, the state of the prior art and level of one of ordinary skill with regard to determining homology, hybridization, and promoter activity is very high. Accordingly, any experimentation necessary to practice the present invention would be merely routine, and accordingly even a "considerable amount of experimentation" would be acceptable.

Furthermore, the Examiner is improperly ignoring the limitations of the claims that require a high degree of similarity between the "variants" and SEQ ID NO:1. The "variants" encompassed by claims 3 and 4 must be 90% homologous to or hybridize under high stringency conditions to SEQ ID NO:1. Given these constraints, it would be unlikely for the "variants" not to have promoter activity. More importantly, however, the skilled artisan would be able to readily determine whether the "variant" in fact had promoter activity.

For the foregoing reasons, Applicants submit that the Examiner is in error, and respectfully request reconsideration of the rejection for lack of enablement.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Pending claim 1 has been allowed by the Examiner. Accordingly, Applicants believe that the present application has been put into condition for allowance, and respectfully request withdrawal of all rejections and allowance of the application.

Respectfully submitted,

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